

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4a

CX/NFSDU 12/34/5-Add.2
Original language only!

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-fourth Session

Bad Soden am Taunus, Germany

3 – 7 December 2012

GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NON-COMMUNICABLE DISEASES FOR GENERAL POPULATION (NRVs-NCD)

(Comments at Step 3 of the procedure)

Comments from:

BRAZIL

COSTA RICA

EUROPEAN UNION

NEW ZEALAND

NIGERIA

RUSSIAN FEDERATION

URUGUAY

BRAZIL

GENERAL COMMENTS

Brazil would like to express its appreciation for the Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-Related Noncommunicable Diseases for General Population (NRVS-NCD) prepared by United States, Thailand and Chile.

Moreover, Brazil thanks for the opportunity to present the following comments on the CX/NFSDU 12/34/5.

SPECIFIC COMMENTS

Attachment A

OPTIONS PRESENTED TO THE EWG FOR FINALIZING TEXT PERTAINING TO STRENGTH OF THE SCIENTIFIC EVIDENCE IN THE PROPOSED DRAFT GENERAL PRINCIPLES FOR NRVS-NCD IN APPENDIX V OF REP 12/NFSDU

Note to CCNFSDU: For reference, below are expanded approaches and options for text in the proposed draft general principles for NRVs-NCD that is related to the strength of the evidence for the relationship between a nutrient and NCD risk (in Section 3.1). The eWG was asked which of these three approaches and six text options they preferred most and least. Based on these comments, the report recommendation is to use text option B1 (highlighted below), which is incorporated into the proposed revision of Appendix V in Attachment B and into the proposed draft consolidated Annex in Attachment C.

APPROACHES AND OPTIONS

Approach A-“Convincing/Generally Accepted” evidence as the sole basis for an NRV-NCD and acknowledge government flexibility in Preamble only. This approach retains “convincing/generally accepted” scientific evidence as the sole basis for establishing a Codex NRV-NCD. In addition, it acknowledges only in the Preamble of the General Principles that governments have the flexibility to consider a lower level of evidence than “convincing/generally accepted”.

Preamble

Option A1 considers that sufficient flexibility is already provided in the following text in the 3rd sentence for governments to consider a lower level of evidence and that this is implicit.

Option A1 proposed text:

“Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below and additional factors specific to a country or region in establishing their own reference values.”

Option A2 considers that the preamble could refer more specifically to levels of evidence.

Option A2 proposed text:

“Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below [**including the level of evidence required,**] and additional factors specific to a country or region in establishing their own reference values.”

Approach B-“Convincing/Generally Accepted” evidence as the sole basis for NRVs-NCD, and acknowledge government flexibility in both the Preamble and Section 3.1. This approach retains “convincing/generally accepted” scientific evidence as the sole basis for establishing a Codex NRV-NCD. In addition, it acknowledges in a separate sentence in the first bullet of 3.1 that governments may consider the suitability of a lower level of evidence that “convincing/generally accepted” in establishing their own food label reference values.

Section 3.1, Second sentence in first bullet

Option B1 (Former Option 1 in Appendix V). This option explicitly acknowledges in 3.1 that governments may consider “probable evidence” in establishing their own food label reference

values. With this option, a definition for “probable evidence” could be included (or a citation for a definition provided), but it may not be required since it would not apply to Codex NRVs-NCD.

Option B1 proposed text:

[In addition, governments may consider the suitability of probable evidence³⁰ in conjunction with other bases in establishing their own food label reference value(s).]

Option B2. This option acknowledges in 3.1 that governments may consider lower levels of evidence in establishing NRV-NCDs without identifying specific descriptors for levels of evidence or definitions.

Option B2 proposed text:

[In addition, governments may consider the suitability of ~~probable evidence~~ [additional/different levels of evidence] in conjunction with other bases in establishing their own food label reference value(s).]

Approach C-Additional Consideration of Evidence Lower than “Convincing/Generally Accepted” for NRVs-NCD and acknowledge government flexibility in Preamble. This approach retains “convincing/general accepted” scientific evidence as a basis for establishing a Codex NRV-NCD, and states or implies that the suitability of lower levels of evidence may also need to be considered in establishing a Codex NRV-NCD.

Option C1- This option allows consideration of “probable” evidence in establishing NRVs-NCD with a specific descriptor and definition (*Former Option 2 in REP 12/NFSDU, Appendix V*). There was general agreement that the criteria for probable evidence used in FAO/WHO data sources currently available for this work (i.e., FNP 91 and TRS 916) was unsuitable. Consequently, Option 2 in Appendix V includes a footnote to an “updated” draft definition adapted from a 2007 World Cancer Research Fund/American Institute for Cancer Research Report (WCRF/AICR Report).

Option C1 proposed text:

[In addition, the suitability of probable evidence may need to be considered.]

Option C2- This option allows consideration of lower levels of evidence in establishing NRVNCDs without identifying specific descriptors for levels of evidence or definition(s). (*Former Option 1 in Appendix V with edits below*). This option considers that the FAO/WHO values based on “probable evidence” currently available for this Committee’s work did not use the definition in the 2007 WCRF/AICR report, and that the WHO representative indicated at the last CCNFSDU session that a new term would replace “probable” evidence (as well as “convincing evidence”).

Option C2 proposed text:

[In addition, the suitability of ~~probable~~ [additional/different] levels of evidence may need to be considered.]

Comments:

In order to reach a consensus, Brazil agrees to accept the Option B1. Thus, we consider important to include a statement in the item 3.1 regarding to the possibility of using probable evidence by the governments, in the same way of the second sentence of the item 3.3.5, that allows governments to derive their own reference values for nutrition labelling based on another reference energy intake that considers factors specific to their country ou region. Moreover, we understand that is important to delete the square brackets from the text “including the level of evidence required” in the preamble of the document, as proposed in the Option A2.

Attachment B

PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING:

GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR NUTRIENTS ASSOCIATED WITH RISK OF DIET-RELATED NONCOMMUNICABLE DISEASES FOR THE GENERAL POPULATION

Note to CCNFSDU: Attachment B incorporates recommendations based on eWG comments for finalizing remaining bracketed text in the first bullet of Section 3.1, Appendix V in REP12/NFSDU. This bracketed text concerns the strength of the evidence for establishing Codex and government food label reference values, and related descriptors and definitions. In addition, two options are proposed for the placement of the NRVNCD definition (and related minor edits) based on eWG comments.

In this attachment, proposed new text is underlined text. Proposed deletions are identified by ~~strikeout~~.

1. PREAMBLE

These principles apply to the establishment of Codex Nutrient Reference Values for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases (NRVs-NCD) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. Governments are encouraged to use the NRVs-NCD, or alternatively, consider the suitability of the general principles below [including the level of evidence required,] and additional factors specific to a country or region in establishing their own reference values for labelling purposes, for nutrients associated with diet-related noncommunicable diseases.

For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. Governments may also consider whether to establish separate food label reference values for specific segments of the general population.

Comments:

Brazil understands that is important to delete the square brackets from the text “including the level of evidence required” in the preamble of the document.

2. DEFINITION(S)

[Option 1: Define NRV-NCD in Section 2 of the Annex on general principles as identified below:

2.1 Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related noncommunicable diseases not including nutrient deficiency diseases or disorders.

Or

Option 2: *Remove the NRVs-NCD definition from this Annex. Instead, propose to CCFL that the new definition of NRVs adopted by the Commission in 2012 for inclusion in Section 2 of the Guidelines be revised to incorporate the terminology, abbreviations, and complete definitions for Nutrient Reference Values-Noncommunicable Disease (NRVs-NCD) and Nutrient Reference Values-Requirements (NRVs-R). The proposed edits are identified below.*

*(new 2.4 in the Guidelines) **Nutrient Reference Values (NRVs)*** are a set of numerical values that are based on scientific data for purposes of nutrition labelling and relevant claims. They include the following two types of NRVs: NRVs are based on levels of nutrients associated with nutrient requirements, or with the reduction in the risk of diet-related noncommunicable diseases.*

Nutrient Reference Values- Requirements (NRVs-R) refer to NRVs that are based on levels of nutrients associated with nutrient requirements.

Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to NRVs that are based on levels of nutrients associated with the reduction in the risk of diet-related noncommunicable diseases not including nutrient deficiency diseases or disorders.

** See also the [Annex] [Annexes] for the General Principles for the Establishment of Nutrient Reference Values.*

Comments:

Brazil agrees with the Option 2.

2.# Daily Intake Reference Values as used in these principles refer to reference nutrient intake values provided by FAO/WHO or other recognized authoritative scientific bodies that may be considered in establishing an NRV-NCD based on the principles and criteria in Section 3. These values may be expressed in different ways (e.g., as a single value or a range), and are applicable to the total population or to a segment of the population (e.g., recommendations for a specified age range).

2.# Upper Level of Intake (UL)³¹ is the maximum level of habitual intake from all sources of a nutrient or related substance judged to be unlikely to lead to adverse health effects in humans.

2.# Acceptable Macronutrient Distribution Range (AMDR) is a range of intakes for a particular energy source that is associated with reduced risk of diet-related noncommunicable diseases while providing adequate intakes of essential nutrients. For macronutrients, they are generally expressed as a percentage of energy intake.

3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-NCD**3.1 Criteria for Selection of Nutrients**

The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:

Relevant convincing³²/ generally accepted³³ scientific evidence for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for relevant disease risk

[, for at least one major segment of the population (e.g., adults).] In addition, governments may consider the suitability of probable evidence³⁴ in conjunction with other bases in establishing their own food label reference value(s).

Public health importance of the nutrient-noncommunicable disease risk relationship(s) among Codex member countries.

Comments:

We agree with the inclusion of the text “ for at least one major segment of the general population (e.g., adults)”, as the principles for establishing NRVs-NCD apply to the establishment of Codex Nutrient Reference Values for labelling purposes for the general population. Thus, we consider appropriate that the scientific evidence refers to one major segment of the general population.

We also agree to include the phrase “In addition, governments may consider the suitability of probable evidence³⁴ in conjunction with other bases in establishing their own food label reference value(s).” in the item 3.1.

Attachment C

*Note to the CCNFSDU:: Below is a **proposed draft consolidation** of the: 1) adopted Annex on general principles for establishing vitamin and mineral NRVs (Annex, CAC/GL 2-1985), and 2) revised proposed draft general principles for establishing NRVs-NCD in Attachment B. In this consolidation, sections are renumbered and certain headings are simplified. In addition, provisions in the adopted Annex are clearly identified by “VM NRV GP”. With a goal to finalize the NRV general principles at the next session, the Committee may wish to focus their review in particular on the bracketed text [.....] and proposed new underlined text. Note: Shaded/highlighted identifies additional minor edits that would result from consolidating the two Annexes.*

Comments:

Brazil would like to point out the definition for “recognized, authoritative, scientific body” discussed in the CX/NFSDU 12/34/8 which may be also applicable in this document.

PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES ON NUTRITION LABELLING:

GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR THE GENERAL POPULATION

1. PREAMBLE

(Slight proposed revision of adopted text in VM NRV GP as a result of consolidation)

These principles apply to the establishment of Codex Nutrient Reference Values (NRVs) for the general population identified as individuals older than 36 months. These values may be used for helping consumers 1) estimate the relative contribution of individual products to overall healthful dietary intake, and 2) as one way to compare the nutrient content between products. Governments are encouraged to use the NRVs, or alternatively, consider the suitability of the general principles below [including the level of evidence required], and additional factors specific to a country or region in establishing their own nutrient reference values for labelling purposes.

For example, at the national level, population-weighted values for the general population may be established by weighting science-based reference values for daily intakes for age-sex groups using census data for a country and proportions of each age-sex group. In addition, governments may establish nutrient reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements. Governments may also consider whether to establish separate food label reference values for specific segments of the general population [such as pregnant and lactating women].

Comments:

Brazil suggests deleting the text “such as pregnant and lactating women” because the sentence is clear enough.

COSTA RICA

Costa Rica agradece al Grupo de trabajo electrónico (GTE) coordinado por Estados Unidos de América, con asistencia de Tailandia y Chile, por la preparación del documento de la referencia. A continuación detallamos nuestra posición con respecto a los aspectos que deberían discutirse en el Comité:

Con respecto al **Anexo A**, Costa Rica apoya la opción B1, que coincide con la recomendación del informe del GTE:

Texto propuesto para la Opción B1:

[Adicionalmente, los gobiernos pueden considerar la idoneidad de la evidencia probable¹ conjuntamente con otras bases para establecer su(s) propio(s) valor(es) de referencia para etiquetas de alimentos]

Consideramos que a nivel de Codex se debe contar solamente con evidencia convincente. Sin embargo, reconocemos la utilidad para los países de considerar aquellos nutrientes con estudios suficientes pero que aún no llegan al nivel “convincente” para el establecimiento de un VRN-ENT. Creemos necesario que la definición de evidencia “probable” aparezca en el texto para asegurar la correcta interpretación del mismo.

La opción de menor preferencia para Costa Rica es la C2, pues consideramos que “diferente/adicional” es un criterio muy ambiguo y no es lo suficientemente robusto, por lo que podría prestarse para disminuir el rigor científico de los estudios en detrimento de la armonización de los criterios para el establecimiento de VRN-ENT.

En cuanto al **Anexo B**, dado que el enfoque B1 no contempla modificaciones en el preámbulo, Costa Rica considera innecesario incluir la frase que se propone y que aparece entre corchetes, sin embargo con el afán de que se avance, tampoco objetaría que aparezca en el preámbulo, pues no contradice el texto propuesto para la opción B1.

Se alienta a los gobiernos a que usen los NRV-NCD, o, de forma alternativa, que consideren la idoneidad de los principios generales que siguen [y que incluyen el nivel de evidencia requerido,] y

¹ Con la opción B1, debería decidirse si incluir o referir a una definición de “evidencia probable”.

factores adicionales específicos a un país o región para establecer sus propios valores de referencia para propósitos del etiquetado, para los nutrientes asociados con enfermedades no-transmisibles relacionadas con la alimentación.

Costa Rica apoya la opción 2 para la definición en cuestión, dado que ya existe una definición para VRN, por lo que cualquier cambio que se proponga debería realizarse ajustando la definición ya aprobada y discutida en el Comité del Codex sobre etiquetado de alimentos.

Opción 2: *Eliminar la definición de NRV-NCD de este Anexo, y proponer al CCFL que se revise la nueva definición de los NRV adoptada por la Comisión en el 2012 para su inclusión en la Sección 2 de las Pautas, para incorporar su terminología, abreviaturas, y definiciones completas para los Valores de Referencia de Nutrientes-Enfermedades No-Transmisibles (NRV-NCD) y los Valores de Referencia de Nutrientes-Requerimientos (NRV-R). Las revisiones propuestas se identifican abajo.*

(Nuevo 2.4 en las pautas) Los Valores de Referencia de los Nutrientes (NRV) son un grupo de valores numéricos basados en datos científicos con el propósito del etiquetado nutricional y reclamos relevantes. Incluyen los siguientes dos tipos de NRV: ~~Los NRV se basan en los niveles de nutrientes asociados con los requerimientos de nutrientes o con la reducción del riesgo de enfermedades no transmisibles relacionadas con la alimentación.~~*

Valores de Referencia de Nutrientes- Requerimientos (NRV-R) se refieren a los NRV basados en niveles de nutrientes que se asocian con los requerimientos de nutrientes.

Valores – Enfermedades No-Transmisibles (NRV-NCD) se refieren a los NRV basados en niveles de nutrientes asociados con la reducción del riesgo de las enfermedades no transmisibles relacionadas con la alimentación excepto las enfermedades o trastornos de deficiencia de nutrientes.

* Véase también el [Anexo] [Anexos] de los Principios Generales para el Establecimiento de Valores de Referencia de Nutrientes

Costa Rica está de acuerdo con la edición propuesta en el punto 3.1, por tanto apoya la remoción de los corchetes alrededor de la frase “para al menos un segmento importante de la población general (p.ej., adultos)”, dado que existen VRN con evidencia convincente para un segmento de la población pero no necesariamente para todos.

Costa Rica también apoya las notas al pie que se proponen. Aunque considera aclaratorio que aparezca en el texto la definición de la evidencia “convincente” y de la evidencia “probable” para facilitar la interpretación correcta de las mismas, comprendemos que éstas podrían cambiar con el tiempo, de manera que mientras quede claro cual es la referencia utilizada, podríamos aceptar el texto tal como se presenta:

3.1 Criterios para la Selección de Nutrientes

Los siguientes criterios deben considerarse en la selección de nutrientes para el establecimiento de NRV-NCD:

Evidencia científica relevante, convincente²/ generalmente aceptada³ para la relación de un nutriente y el riesgo de enfermedad no-transmisible, incluyendo los marcadores biológicos validados para el riesgo de la enfermedad relevante [, para por lo menos un segmento importante de la población (ej., adultos).] Adicionalmente, los gobiernos pueden considerar la idoneidad de la evidencia probable⁴

² Al momento de la redacción de estos principios orientadores, se usaban la definición y los criterios de “evidencia convincente” de los siguientes informes FAO/OMS: 1) *Fats and Fatty Acids in Human Nutrition: Report of an Expert Consultation*. FAO Food and Nutrition Paper 91. Rome, FAO, 2010. and 2) *Diet, Nutrition and the Prevention of Chronic Diseases*. Serie 916 de informes técnicos de la OMS, 2003.

³ Para estos principios generales los términos evidencia convincente/generalmente aceptada se consideran sinónimos.

⁴ Donde procede, los gobiernos pueden adaptar la definición y criterios de “evidencia probable” del siguiente informe del Fondo Mundial para la Investigación del Cáncer y el Instituto Americano para la Investigación del Cáncer: *Food, Nutrition, Physical Activity, and the Prevention of Cancer: a Global Perspective*. Washington DC: AICR, 2007, p.60.

en conjunto con otros fundamentos para establecer su(s) propio(s) valor(es) de referencia para etiquetas de alimentos.

Con respecto al **Anexo C**, Costa Rica considera que podría ser más amigable para los gobiernos, el contar con un anexo consolidado para el establecimiento de VRN. Dado que el texto aprobado y el que se continúa discutiendo son bastante similares, no debería haber atrasos considerables en la revisión del anexo consolidado. Además, está de acuerdo con la organización propuesta de consolidación de los dos Anexos, tal como aparece en el Anexo C. Apoya la eliminación del término “nutriente” en dos sitios del Preámbulo, pero no considera necesaria la frase entre corchetes “tales como mujeres embarazadas y que amamantan”.

En cuanto a los aspectos discutidos sobre la **necesidad de NRV-NCD adicionales**, Costa Rica considera apropiado el uso de los dos informes de FAO/OMS FNP 91 y TRS 916 como punto de partida inicial para identificar nutrientes con un nivel de evidencia convincente.

Apoyamos lo anotado en el informe en cuanto a que podrían requerirse actualizaciones de la OMS y FAO para la próxima sesión del Comité, sobre nuevos procedimientos para obtener asesoramiento científico conjunto de FAO/OMS sobre nutrición. También consideramos que sería útil aclarar si con este proceso es posible que la Comisión acceda fácilmente a los resultados científicos de evaluación de riesgos y las recomendaciones basadas en las revisiones sistemáticas de la bibliografía científica, con independencia del asesoramiento sobre manejo de riesgo de la OMS que considera la información adicional, y aclarar de qué manera este proceso se relaciona con los principios de análisis de riesgo del Codex.

Costa Rica apoya la observación de que al igual que en el grupo de trabajo electrónico sobre NRV de vitaminas y minerales, se considere desarrollar una definición para organismo científico competente reconocido a fin de ayudar en la aplicación del Principio general 3.2.2. En este sentido, apoya la definición propuesta en dicho grupo:

“Organismo científico competente reconocido

Se entiende, a los efectos de establecer valores de referencia de nutrientes del Codex, toda organización apoyada por uno o varios Gobiernos para ofrecer asesoramiento científico independiente y competente sobre los valores de referencia de la ingesta dietética, y cuyo asesoramiento está reconocido al usarse en la elaboración de políticas en [al menos][más de un] país.”

Consideramos que debería quedar el texto entre corchetes que dice “más de un” país, de manera que sea un organismo cuyas recomendaciones no solo se conozcan en el país en el que se ubica tal organismo, sino que otros países lo utilicen para el establecimiento de sus propios valores de referencia.

Costa Rica considera que deben incluirse VRN-ENT adicionales que tengan evidencia convincente en lugar de limitarse únicamente a aquellos que se incluyen en el punto 3.2.1.2 de las Directrices sobre Etiquetado Nutricional. Sin embargo apoyamos el uso de dicha lista como punto de partida en concordancia con la Estrategia Mundial de la OMS sobre Alimentación, actividad física y salud.

En cuanto al Anexo D, Costa Rica apoya las modificaciones planteadas por el grupo de trabajo electrónico para la sección 3.4.4 de las Directrices de Etiquetado Nutricional.

Según la información que se aporta en el Anexo F, Costa Rica estaría de acuerdo en que se revise el VRN de proteínas con el fin de actualizar dicho valor a la luz de los nuevos conocimientos.

EUROPEAN UNION

The European Union (EU) would like to thank the United States, Thailand and Chile for leading the work of the electronic working group and for preparing the discussion document.

The EU has the following comments on attachment B 'Proposed draft general principles for establishing nutrient reference values for nutrients associated with risk of diet-related noncommunicable diseases for general population (NRVS-NCD)':

Preamble

The EU supports the additional text [including the level of evidence required], which clarifies that the flexibility given to Governments encompasses the level of scientific evidence required.

Definition(s)

The EU supports option 2. The EU believes that a definition for NRVs related to nutrient requirements (NRV-R) is necessary to better distinguish the notions of NRV-R and NRV-NCDs. The presence of the definition for NRV-NCDs leads to the necessity of a corresponding definition for NRV-R.

The EU would see the benefit of grouping all these definitions in the corresponding section 2 of the Guidelines, especially if these terms are mentioned before the Annex to the Guidelines in section 3.4.4.

The EU also supports the text of the proposed definitions of NRV-R and NRV-NCDs.

General principles to establish NRVs-NCD

The EU supports the proposed text [, for at least one major segment of the population (e.g. adults)], as it clarifies that convincing evidence is not required for each subpopulation group. A convincing level of evidence established for adult appears sufficient in the context of the impact of nutrient intake on non-communicable chronic diseases. Ethical reasons can also prevent the development of scientific evidence among subgroups.

The EU does not support the reference to probable evidence and suggests the deletion of the text 'In addition, governments may consider the suitability of probable evidence in conjunction with other bases in establishing their own food label reference value(s).'

The NRVs, based on the Codex Guidelines, should remain based on convincing evidence, and flexibility should be introduced only at the level of the use of the Guidelines, in the preamble. The term 'probable' in the paragraph entitled 'principles ...' may also water down all the principles and open discussion for a wider use of this term, especially in the context of the level of evidence required for the substantiation of health claims.

Definition of convincing evidence – footnote 32

The EU notes that the report Fats and Fatty Acids in Human Nutrition: Report of an Expert Consultation provides the same definition and mentions the report Diet, Nutrition and the Prevention of Chronic Diseases as the source of this definition.

The EU would therefore find sufficient the footnote to be introduced in paragraph 3.1 to indicate only that the definition of "convincing" is included in the WHO/FAO Technical Report Series 916 Diet, Nutrition and the Prevention of Chronic Diseases.

Definition of probable evidence –footnote 34

The EU, supporting the deletion of the text to which the footnote is attached, is consequently in favour of the deletion of this footnote.

NEW ZEALAND

New Zealand appreciates the opportunity to contribute to the work on the review of the General Principles on the Addition of Essential Nutrients to Foods and is thankful to the US, Thailand and Chile in chairing this work.

Section 3.1 Strength of evidence

New Zealand supports the proposal to use option B1 wording in Section 3.1 in addition to text in the Preamble which allows governments the flexibility to establish food label reference values based on lower levels of evidence, such as 'probable evidence'. This allows for consideration of deriving reference values for lower levels of evidence in future assessments by WHO/FAO.

Option B1 wording:

[In addition, governments may consider the suitability of probable evidence³⁰ in conjunction with other bases in establishing their own food label reference value(s).]

New Zealand considers that one of the remaining issues with Section 3.1 is the reference to and definitions of “probable” and “convincing”. The terms, particularly “probable”, have been problematic in interpretation and understanding within the electronic working group. As recognised in the discussion paper, the terms “probable” and “convincing” will no longer be used by the WHO in Guideline development and that the GRADE system is now the preferred tool for assessing the quality of evidence. It is also noted that there are no nutrients for which there is only probable evidence for a nutrient NCD relationship in either the FNP91 or TRS 916 reports, therefore any amendments to the definition of probable will only be valid for future guidelines produced by WHO/FAO.

As New Zealand considers that the definition for “probable” continues to be problematic, we propose that clarification of meaning consistent with the WHO grading system could be an alternative approach sought by the Committee. This would allow for the definition to remain relevant with the release of new Guidelines.

Classification according to the GRADE profiling system adopted by the WHO Guideline Development Handbook is comprised of two parts; evaluation of the evidence and strength of the recommendation. New Zealand proposes that only the first classification system is used for the derivation of a NRV-NCD for labelling purposes as it is most consistent with the FNP 91 and TRS 916 method to evaluate the overall quality of evidence and is based solely on the evaluation of the evidence between the nutrient and NCD. In the second step the strength of recommendation also takes into account benefit-harms evaluation, consumer values and preferences, and costs. New Zealand does not consider that the strength of a recommendation of a WHO guideline document may necessarily be relevant if the recommendation has not derived for the same purposes as Codex NRV-NCD for labelling purposes.

Assessing the overall quality of evidence is defined as “the extent to which one can be confident that an estimate of effect or association is correct.” The following criteria are taken into account to grade the evidence:

- The study design
- The consistency of the results across the available studies
- The precision of the results
- The directness of the evidence with respect to populations, interventions and settings where the proposed intervention may be used
- The likelihood of publication bias

Table 1 presents the GRADE classifications for levels of quality of evidence and the definitions as they stand in 2012. New Zealand considers that a ‘high’ level of evidence is equivalent to the level of evidence required for “convincing evidence” and that ‘moderate’ would be the equivalent to “probable level of evidence”.

The use of the new WHO Guideline development approach and reference to it within the text would preclude the use of a long prescriptive definition in the Annex, would be in line with current WHO methods, and may be less confusing to national authorities than adapting definitions from the World Cancer Report.

Table 1: GRADE definitions in the WHO Handbook for Guideline Development (2012)*

Grade	Definition
High	The guideline development group is very confident that the true effect lies close to that of the estimate of the effect
Moderate	The guideline development group is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low	Confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the true effect
Very Low	The group has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect

*http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf

New Zealand therefore proposes the following amendments to the text:

Relevant convincing³⁷/generally accepted³⁸ scientific evidence for the relationship between a nutrient and noncommunicable disease risk relationship, including validated biomarkers for relevant disease risk [, for at least one major segment of the population (e.g. adults,]. In addition, governments may consider the suitability of ~~probable~~ a moderate level of evidence³⁹ in conjunction with other bases in establishing their own food label reference value(s).]

³⁷At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO reports were used: 1) *Fats and Fatty acids in Human Nutrition: Report of an Expert Consultation*. FAO Food and Nutrition Paper 91. Rome, FAO, 2010. and 2) *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916. WHO 2003. **This definition is considered equivalent to the definition and criteria for a “high” level of evidence as defined in the WHO Handbook for Guideline Development. WHO 2012.**

³⁸For these General Principles the terms convincing/generally accepted evidence are considered synonymous

³⁹Where applicable, the definition and criteria for a “**moderate**” level of evidence from the **WHO Handbook for Guideline Development (2012)** may be used by governments for this purpose.

New Zealand considers that terms should be clearly defined and the levels of evidence should be linked to the WHO grading systems since any future WHO/FAO guideline documents are likely to be following the new WHO grading system.

Consolidation of the two annexes

New Zealand is supportive of combining the two annexes and finalising the consolidated Annex in Attachment C and the proposed new organisation of Section 3.

Paragraph 65: Of the two approaches proposed to define the NRVs, New Zealand is supportive of Option 2 as it clearly distinguishes between the types of NRVs.

Paragraph 68: New Zealand supports the minor edits to the preamble, but proposes that the bracketed text referring to pregnant and lactating women is deleted. The example is not necessary and is not considered applicable to NRVs-NCD.

Need for additional NRVs-NCD

Paragraph 76-78: New Zealand considers the two FAO/WHO reports, FNP91 and TRS916, are appropriate initial starting points for identifying nutrients with a convincing level of evidence.

Paragraph 82: The definition of RASB is also under consideration in the NRVs-R agenda item. New Zealand supports working towards development of a definition that can be used for both purposes.

Paragraph 89: New Zealand does not support limiting establishment of NRVs-NCD to those nutrients listed in 3.2.1.2 of the Guidelines as an NRV-NCD convincing relationship has not been established for many of these nutrients (i.e. total fat, available carbohydrates, protein). The list in 3.2.1.2 and the WHO Global Strategy can be used as a means to prioritise nutrients for review. It would also seem prudent to find out the expected timeframe for the completion of the WHO NUGAG Subgroup on Diet and Health systematic reviews of total fats and sugars, sodium and potassium, and trans fat. If they are expected to be published shortly it would be logical to use these as a basis for informing any additional NRVs-NCD for labelling purposes.

Paragraph 109: New Zealand supports that two types of NRV could be considered on a case-by-case basis but does not consider that at this time there is a compelling reason to establish two NRVs for any one nutrient. The establishment of two types of NRVs must be accompanied with guidance on how they are to be used in nutrition labelling so as not to confuse the consumer.

Interest in proposing new work related to NRVs for protein, total fat and/or available carbohydrate

New Zealand supports the proposal for new work to review the protein NRV as the value currently in the Guidelines is over 25 years old and suitable updates are available. However New Zealand does not consider that establishing an NRV for fat or available carbohydrates is a priority for focus of the CCNFSDU at this stage.

NIGERIA

Nigeria wishes to commend the United States of America, Thailand, Chile and other members of the electronic work group for preparing this draft principle at step 4, and also to make the following comments:

Attachment A

APPROACHES AND OPTIONS

Nigeria supports the proposal that the Approach B and text option B1 be incorporated.

Justification: This is because in addition to emphasizing the use of convincing/generally acceptable evidence as sole source for NRV-NCDs, there may be situations that Governments may need to set NRC-NCDs based on “probable evidence”. The option gives room for the later when needed.

On approach C, we do not support the use of lower evidence in establishing a Codex NRV. However, Governments should be given the flexibility to use “probable evidence” to do so if they see a justification for it.

Attachment F

Nigeria supports the (DRAFT PROJECT DOCUMENT) Proposal to Review the Nutrient Reference Value for Protein in the Guidelines on Nutrition Labelling (CAC/GL 2-1985) in light of scientific Updates.

RUSSIAN FEDERATION

Пожалуйста, примите для рассмотрения следующую поправку к тексту приложения E Please:

Потенциальные источники соответствующих данных для оценки весомости доказательств в дополнение к источникам данных ФАО/ВОЗ для вышеупомянутого документа.

Другие источники потенциальных данных /Списки по странам

Россия

НИИ питания Российской академии медицинских наук

Примечание:

Институт питания РАМН является единственной в РФ научной организацией, ведущей исследования в области специализированного питания и пищевых продуктов, а также в области

разработки научной базы для установления NRVs-NCD. Институт обладает высококвалифицированным персоналом и необходимой компетенцией, а также имеет клинику, занимающуюся вопросами влияния факторов питания на здоровье. Кроме того, НИИ питания активно сотрудничает с FAO, WHO, WTO, ILSI, ESPGHAN, University of Nord Caroline и другими национальными институтами питания в различных странах.

URUGUAY

Uruguay agradece a los Estados Unidos, Tailandia y Chile la preparación de este documento y la oportunidad de realizar los siguientes comentarios:

	COMENTARIOS DE URUGUAY
<p>PREÁMBULO</p> <p>Estos principios se aplican al establecimiento de Valores de Referencia para Nutrientes en el Codex para propósitos del etiquetado para nutrientes asociados con el riesgo de enfermedades no-transmisibles (NRV-NCD) para la población general que se identifica como los individuos mayores de 36 meses. Estos valores pueden usarse para ayudar a los consumidores a 1) estimar el aporte relativo de productos individuales a una ingesta alimenticia total sana, y 2) como una forma de comparar el contenido de nutrientes entre productos. Se alienta a los gobiernos a que usen los NRV-NCD, o, de forma alternativa, que consideren la idoneidad de los principios generales que siguen [<u>y que incluyen el nivel de evidencia requerido,</u>] y factores adicionales específicos a un país o región para establecer sus propios valores de referencia para propósitos del etiquetado, para los nutrientes asociados con enfermedades no-transmisibles relacionadas con la alimentación.</p>	<p>URUGUAY ESTA A FAVOR DE QUITAR LOS CORCHETES E INCLUIR ESTA ACLARACIÓN</p>
<p>(Nuevo 2.4 en las pautas) Los Valores de Referencia de los Nutrientes (NRV)* son un grupo de valores numéricos basados en datos científicos con el propósito del etiquetado nutricional y reclamos relevantes. Incluyen los siguientes dos tipos de NRV: Los NRV se basan en los niveles de nutrientes asociados con los requerimientos de nutrientes o con la reducción del riesgo de enfermedades no-transmisibles relacionadas con la alimentación.</p> <p>Valores de Referencia de Nutrientes- Requerimientos (NRV-R) se refieren a los NRV basados en niveles de nutrientes que se asocian con los requerimientos de nutrientes.</p> <p>Valores – Enfermedades No-Transmisibles (NRV-NCD) se refieren a los NRV basados en niveles de nutrientes asociados con la reducción del riesgo de las enfermedades no transmisibles relacionadas con la alimentación excepto las enfermedades o trastornos de deficiencia de nutrientes.</p>	<p>TENIENDO EN CUENTA TODO LO TRABAJADO, URUGUAY ACUERDA CON LA OPCIÓN 2, INCLUYENDO LA REDACCIÓN SUBRAYADA Y ELIMINANDO LO TACHADO</p>
<p>Evidencia científica relevante, convincente/ generalmente aceptada para la relación de un nutriente y</p>	<p>URUGUAY ACUERDA QUITAR LOS CORCHETES PARA</p>

<p>el riesgo de enfermedad no-transmisible, incluyendo los marcadores biológicos validados para el riesgo de la enfermedad relevante [, para por lo menos un segmento importante de la población (ej., adultos).] Adicionalmente, los gobiernos pueden considerar la idoneidad de la evidencia probableiii en conjunto con otros fundamentos para establecer su(s) propio(s) valor(es) de referencia para etiquetas de alimentos;</p>	<p>INCLUIR EL TEXTO SUBRAYADO. EN CONSISTENCIA CON LA POSICIÓN QUE SE HA TENIDO HASTA EL MOMENTO NO SE APOYARÍA LA FRASE QUE ESTÁ A CONTINUACIÓN POR LO QUE SE TACHA.</p>
---	---

Anexo C

BORRADOR DEL ANEXO PROPUESTO A LAS PAUTAS DEL CODEX SOBRE EL ETIQUETADO NUTRICIONAL:

PRINCIPIOS GENERALES PARA ESTABLECER VALORES DE REFERENCIA DE NUTRIENTES PARA LA POBLACIÓN GENERAL

<p>1. PREÁMBULO</p> <p><i>(Revisión leve propuesta para el texto adoptado en VMNRV GP como resultado de la consolidación)</i></p> <p>Estos principios se aplican al establecimiento de Valores de Referencia de Nutrientes del Codex (NRV) para la población general identificada como los individuos mayores de 36 meses. Estos valores pueden usarse para ayudar a los consumidores a que 1) estimen el aporte relativo de los productos individuales a la ingesta dietética total sana, y 2) como una forma de comparar el contenido de nutrientes entre productos. Se alienta a los gobiernos usar los NRV, o, como alternativa, considerar la idoneidad de los principios generales que siguen [<u>incluyendo el nivel de evidencia requerida</u>], y los factores adicionales específicos al país o región al establecer sus propios valores de referencia de nutrientes para el etiquetado.</p>	<p>URUGUAY ESTA A FAVOR DE QUITAR LOS CORCHETES E INCLUIR ESTA ACLARACIÓN</p>
<p>Los Valores de Referencia de Nutrientes- Requerimientos (NRV-R) se refieren a los NRV basados en los niveles de nutrientes asociados con los requerimientos de nutrientes.</p> <p>Los Valores de Referencia de Nutrientes – Enfermedades No-Transmisibles (NRV-NCD) se refieren a los NRV que se basan en los niveles de nutrientes asociados con la reducción en el riesgo de las enfermedades no-transmisibles con la excepción de las enfermedades o trastornos de deficiencia de nutrientes</p>	<p>TENIENDO EN CUENTA TODO LO TRABAJADO, URUGUAY ACUERDA CON LA OPCIÓN 2, INCLUYENDO LA REDACCIÓN SUBRAYADA Y ELIMANDO LO TACHADO</p>
<p>2.4 (definición adoptada- VM GP) Nivel de Nutriente Individual 98 (INL₉₈)^{iv} es el [valor de ingesta diaria de nutrientes] [valor de referencia de ingesta diaria] estimado para cumplir con el requerimiento de nutrientes del 98 por ciento de los individuos aparentemente sanos en una cierta etapa de vida y sexo</p>	<p>URUGUAY ACUERDA CON QUITAR CORCHETES EN LA PRIMERA FRASE Y ELIMINAR LA SEGUNDA REDACCIÓN PROPUESTA, POR LO QUE SE TACHA</p>
<p>3.2.1.2 (adoptado VM NRV GP) Los NRV-R para la población general deben determinarse calculando los</p>	<p>URUGUAY ACUERDA EN QUITAR</p>

valores promedios para una población de referencia elegida de mayor de 36 meses. Los [Valores de Referencia de Nutrientes] [NRV-R] derivados por el CCNFSDU están basados en el rango etario más amplio tanto para hombres adultos como para mujeres adultas.	LOS CORCHETES
La evidencia científica relevante convincente/ generalmente aceptada para la relación entre un nutriente y el riesgo de una enfermedad no-transmisible, incluyendo marcadores biológicos validados para el riesgo relevante de la enfermedad [, para por lo menos un segmento importante de la población (ej., adultos).] Adicionalmente, los gobiernos pueden considerar la idoneidad de la evidencia probable en conjunto con otros fundamentos al establecer su(s) propio(s) valor(es) de referencia para etiquetas de alimentos.	URUGUAY ACUERDA QUITAR LOS CORCHETES PARA INCLUIR EL TEXTO SUBRAYADO. EN CONSISTENCIA CON LA POSICIÓN QUE SE HA TENIDO HASTA EL MOMENTO NO SE APOYARÍA LA FRASE QUE ESTÁ A CONTINUACIÓN POR LO QUE SE TACHA.

Anexo D

Borrador de Enmiendas Propuestas a la Sección 3.4.4 de las Pautas del Etiquetado Nutricional (CAC/GL 2-1985)

<p>3.4.4 La información numérica sobre las vitaminas y minerales debe expresarse en unidades métricas y/o como un porcentaje del <u>NRV</u> Valor de Referencia de Nutrientes por 100 g o por 100 ml o por paquete si el paquete contiene una sola porción. Adicionalmente, esta información puede entregarse por porción como cuantificada en la etiqueta o por porción siempre que el número de porciones contenidas en el paquete está presente.</p> <p>Adicionalmente, la información sobre la proteína y nutrientes adicionales también puede expresarse como porcentajes del <u>NRV</u> Valor de Referencia de Nutrientes.^{viii} <u>en los que se ha establecido un NRV.</u></p>	URUGUAY ESTÁ DE ACUERDO CON AGREGAR LA FRASE SUBRAYADA, ES CONSISTENTE CON LA NORMATIVA ACTUAL
Los siguientes NRV Valores de Referencia de Nutrientes son para la población general identificada como individuos mayores de 36 meses. Deben usarse para el etiquetado para ayudar a que los consumidores logren una ingesta alimenticia total sana. en los intereses de la estandarización y armonización internacional	URUGUAY ESTÁ DE ACUERDO CON LAS FRASES SUBRAYADAS Y QUITAR LO QUE ESTÁ TACHADO
<p>Opción 2 (si los términos y abreviaturas y definiciones relacionadas para los NRV-R y los NRV-NCD se introducen anteriormente en la Pauta en la Sección 2)</p> <p>[Incluyen dos tipos de NRV: Valores de Referencia de Nutrientes-Requerimientos (NRV-R) y Valores de Referencia de Nutrientes – Enfermedades No-Transmisibles (NRV-NCD).41]</p>	URUGUAY ACUERDA CON LA OPCIÓN 2
<p><u>3.4.4.2 NRV-NCD</u></p> <p><i>Nota para eWG: En la nueva sección 3.4.4.2 que se</i></p>	URUGUAY ESTÁ DE ACUERDO EN CONCORDANCIA CON LO APROBADO EN EL CCFL (COMITÉ DE ETIQUETADO)

<i>propone, los NRV-NCD se enumerarían con las notas de pie relacionadas.</i>	
<u>Ácidos grasos saturados</u> 20g ^{ix x}	
<u>Sodio</u> 2000 ⁴³ mg	

Anexo F**BORRADOR DEL DOCUMENTO DEL PROYECTO****PROPUESTA PARA REVISAR EL VALOR DE REFERENCIA DE PROTEÍNA EN LAS PAUTAS PARA EL ETIQUETADO NUTRICIONAL (CAC/GL 2-1985) A LA LUZ DE ACTUALIZACIONES CIENTÍFICAS**

	EN LA RESPUESTA AL ÚLTIMO DOCUMENTO DEL GRUPO ELECTRÓNICO URUGUAY NO ESTABA DE ACUERDO EN HACER UNA REVISIÓN DEL VD PARA PROTEÍNAS, NO OBSTANTE TENIENDO EN CUENTA LA FUNDAMENTACIÓN ACTUAL, LA POSICIÓN ES FAVORABLE A QUE SE REALICE.
--	---